K050345 1/2

# 510(K) SUMMARY


**Company:** ConSeal International, Inc.
90 Kerry Place, Suite 2
Norwood, MA 02062


JAN - 7 2010


**Contact:** Stephen C. Perry, President
Telephone: 781-278-0010 / Facsimile: 781-278-0028
Email: sperry@consealint.com


**Date of Preparation:** January 5, 2010

**Device Name (proprietary):** MendaSil™ TWG Skin and Wound Gel

**Common Name:** Moist Wound Filler OR
Amorphous Hydrogel Wound Dressing

**Classification Name:** Dressing, wound and burn, hydrogel w/drug and/or biologic

**Classification:** Unclassified

**Product Code:** FRO, MGQ

**Legally Marketed Devices for substantial equivalence comparison:**
MendaSil™-TWG Skin and Wound Gel is substantially equivalent to:

| | |
|---|---|
| SilvaSorb Silver Antimicrobial Wound Gel | K011994 |
| AcryDerm Silver Antimicrobial Wound Gel (AcryMed, Inc., OR) | K011994 |
| Silver Shield Antimicrobial Skin and Wound Gel (Anacapa Tech., Inc., CA) | K062212 |

**Description of Device:**
MendaSil™ TWG Skin and Wound Gel is an amorphous wound moisture management gel that helps maintain a moist wound environment that is conducive to healing by either absorbing the wound exudates or donating the moisture. The Gel contains a silver compound that is an effective barrier to bacterial penetration by inhibiting the growth of a broad spectrum of microorganisms which come into contact with the gel. MendaSil™-TWG Skin and Wound Gel will be supplied in conventional HDPE bottles fitted with a "flip top" dispenser closure. This bottle will be placed in a chipboard dispenser box with a package insert.

**Intended Use of the Device:**
MendaSil™-TWG Gel Skin and Wound Gel is indicated for use under the supervision of a healthcare professional for management of partial to full thickness wounds from mild to moderate exudate such as Stage I-IV Pressure Ulcers, Partial and Full Thickness Wounds, 1st and 2nd Degree Burns, Diabetic Foot Ulcers, Venous Stasis Ulcers and Surgical Incision Wounds. The Gel can also be used for management of minor cuts, scrapes/abrasions, and irritated skin.

**Device Technological Characteristics:**
MendaSil™-TWG Skin and Wound Gel exhibits the capacity to absorb moisture and control light wound exudates. The Gel contains a silver compound that acts as an effective barrier to a wide spectrum of bacteria which come into contact with the gel. Hydrogel characteristics are imparted by an inert viscosity enhancing agent as contained in the predicate device (AcryDerm Silver Antimicrobial Wound Gel, Acrymed, Inc., OR aka Silvasorb™ Antimicrobial Wound Gel, #K011994, and Silvershield™ Antimicrobial Skin and Wound Gel #K062212.) MendaSil™-TWG Skin and Wound Gel represents substantial equivalence to the predicate devices.

**Manufacturing:**
MendaSil™-TWG Skin and Wound Gel will be manufactured according to product specifications and under the guidelines of Good Manufacturing Practices (GMP). Risk analysis has been performed to identify possible failure mode during manufacturing. Manufacturing controls have been developed and implemented to address the identified risk factors based on the criticality of the failure mode. All established GMPs will assure that the device manufactured meets all the established specifications prior to release and is safe and effective for its intended use.

**Performance Testing:**
USP Preservative Efficacy and Kirby Bauer Zone Inhibition Testing were performed to establish that MendaSil™-TWG Skin and Wound Gel is an effective antimicrobial barrier. The tests were performed using the test organisms in accordance with USP and some additional bacterial strains. Biocompatibility has been assessed according to Part-1 of the ISO Standard (Biological Evaluation of Medical Devices), [Cytotoxicity, Sensitization, Skin Irritation]. The cytotoxicity was between none and slight. There was no irritation or sensitization.

**Substantial Equivalence Discussions:**
MendaSil™-TWG Skin and Wound Gel is a combination product within the meaning of section 503(g) of the Federal Food, Drug, and Cosmetic Act (Act) and Title 21 of the Code of Federal Regulations (CFR) section 3.2(e)(1) and (2). In accordance with section 503(g)(1) of the Act and 21 CFR section 3.4, MendaSil™-TWG Skin and Wound Gel has two modes of action. One action of the product is the device components' action to provide moisture to dermal wounds and inflamed skin. Another mode of action of the product is that of the silver contained in the hydrogel which acts as a barrier to bacterial penetration by inhibiting the growth of a broad spectrum of microorganisms which come into contact with the hydrogel. This latter barrier action of silver is limited to within the hydrogel. The primary mode of action of the combination product is attributable to the device components' action to provide moisture to dermal wounds and inflamed skin.

The indications of use, technological properties, performance testing described above, for the MendaSil™-TWG Skin and Wound Gel are substantially equivalent to those of predicate device AcyrDerm™ Silver Antimicrobial Wound Gel, Acrymed, Ind., OR aka Silvasorb™ Antimicrobial Wound Gel, #K011994 and Silvershield™ Antimicrobial Skin and Wound Gel #K062212. The performance testing exceeds the requirements as set forth by USP as well exceeds those demonstrated by the predicate devices. The biocompatibility testing and the performance testing performed for the device also demonstrated that the device is safe and effective for the indications of use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Conseal International, Inc.
% Mr. Stephen C. Perry
President & CEO
90 Kerry Place, Suite 2
Norwood, Massachusetts 02062

JAN - 7 2010

Re: K090345
Trade/Device Name: MendaSil™ TWG Skin and Wound Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 9, 2009
Received: December 28, 2009

Dear Mr. Perry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090345/S3 1/1

# Indications for Use Form

## Indications for Use

510(k) Number (if known): K090345/S3

Device Name: MendaSil™ TWG Skin and Wound Gel

Indications for Use:

MendaSil™-TWG Gel Skin and Wound Gel is indicated for use under the supervision of a healthcare professional for management of partial to full thickness wounds from mild to moderate exudate such as Stage I-IV Pressure Ulcers, Partial and Full Thickness Wounds, 1st and 2nd Degree Burns, Diabetic Foot Ulcers, Venous Stasis Ulcers and Surgical Incision Wounds. The Gel can also be used for management of minor cuts, scrapes/abrasions, and irritated skin.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K090345